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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/24/01 08/24/01 08/24/01 08/24/01

020006 M022/0824
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EXAMINER

1400117

ART UNIT	PAPER NUMBER
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3745

7

DATE MAILED: 08/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/724,860

Applicant(s)

WELCHER ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-42 and 46-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-8, 10, 11, and 43-45 in Paper No. 6 and telephonic election of SEQ ID Nos: 4 and 5 are acknowledged. The restriction requirement is made FINAL. Claims 1-56 are pending in this application. Claims 9, 12-42, and 45-56 are withdrawn from consideration as being drawn to a non-elected invention. The elected Group has been examined in light of the elected sequences.

Specification

2. The specification is objected to because the priority data is missing. MPEP 201.11 states that

When the nonprovisional application is entitled to an earlier U.S. effective filing date of one or more provisional applications under 35 U.S.C. 119(e), a statement such as "This application claims the benefit of U.S. Provisional Application No. 60/---, filed ---, and U.S. Provisional Application No. 60/ ---, filed ---." should appear as the first sentence of the description.

The Examiner notes also that the instant application is referred to as a continuation of provisional application 60/169720. A continuation under 35 U.S.C. 120 claims priority to a nonprovisional application and the disclosure is the same as the parent application.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-8, 10, 11, and 43-45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-8, 10, 11, and 43-45 are drawn to a polynucleotide encoding an "IFN-like" protein, methods of expressing same, and compositions thereof. The claimed polynucleotide is not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148

U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Applicant has presented evidence that the protein encoded by the claimed polynucleotide alters tyrosine phosphorylation. However, this effect does not endow the invention with a utility. Tyrosine phosphorylation is increase in response to many factors having many different effects. Robinson et al. (Oncogene, 2000, vol. 19, pp. 5548-5557), for example, teaches that protein tyrosine kinases are involved in "growth, differentiation, adhesion, motility, and death" and that they play roles in "many disease states" (p.5548). Thus an increase in tyrosine phosphorylation provides no guidance as to the function of the encoded protein. There is no indication as to how it affects cells or how it might be used in any beneficial way. Further, while applicant lists a number of diseases in which IFN-L might be involved (pp. 81-82), the specification does not disclose any diseases or conditions known to be associated with it. Merely listing a number of

possibilities is not sufficient to identify or confirm a “real world” context of use; clearly further research would be required to identify a disease in which the encoded protein is involved.

Similarly, identification of binding proteins and assays for the presence of the protein, when the function and significance of the protein are not known, would not be substantial utilities: there is no identifiable benefit for such procedures. Thus, further research is required to identify a disease for which the encoded protein could be used, or a disease for which its presence would be diagnostic. See *Brenner v. Manson*, noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” A patent is therefore not a license to experiment.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material. The specification fails to assert any activity for the encoded protein other than induction of tyrosine phosphorylation. As stated above, this property does not endow the protein with a utility and provides no evidence as to its function. Many soluble factors increase tyrosine phosphorylation of intracellular proteins and there is no well-known or immediately apparent use suggested by this observation. Applicant has provided no guidance as to what proteins are phosphorylated and what such phosphorylation would indicate about how IFN-L could be used. Further, while the name “IFN-L” indicates that the protein is related to interferons, applicant has provided no teaching that such is that case and no guidance to indicate that the protein could function like an interferon. There is no evidence that the protein could be used as an anti-viral or anti-cancer agent or that it has any of the particular biochemical characteristics of interferons as described by Jonash et al. (*The Oncologist*,

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2001, vol. 6, pp. 34-55) for example. Thus there is no well-established utility associated with the disclosed properties of IFN-L and thus no well-established utility associated with the encoding polynucleotide.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8, 10, 11, and 43-45 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 1-8, 10, 11, and 43-45 are further rejected under 35 U.S.C. 112, first paragraph, because, were a utility established, the specification, while being enabling for a polynucleotide comprising SEQ ID NO: 4 or encoding a polypeptide comprising SEQ ID NO:5, would not reasonably provide enablement for variants, sequences identified by hybridization, and fragments of the polynucleotide. As stated above, the biological function, activity, or essential properties of IFN-L are not defined. No particular activity, conserved regions or structures required for function are set forth. Since the biological activity or essential characteristics of the parent polypeptide are therefore not defined in the specification, one of skill in the art would not be able to make nucleic acid fragments or variants encoding polypeptides possessing the same activity or properties as the claimed invention. The amino acid sequence of a polypeptide determines its

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structural and functional properties, and predictability of which amino acids can be substituted is extremely complex and well outside the realm of routine experimentation, because accurate predictions of a polypeptide's structure from mere sequence data are limited. Since detailed information regarding the structural and functional requirements of IFN-L is lacking, it is unpredictable as to which sequence encoding fragments and variations, if any, would have the properties of IFN-L. Therefore, without further guidance as to the essential properties of IFN-L, it would require undue experimentation by one of skill in the art to make and use the invention.

8. Claim 1, 2, 4-8, 10, 11, and 43-45 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants' referral to the deposit of PTA-976 in the specification and in claims 1 and 2 is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to

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recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

9. Claims 1-8, 10, 11, and 43-45 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has disclosed two polynucleotide sequences and encoded polypeptides. However, the claims include fragments and homologues, and thus encompass polynucleotides that vary substantially in length and also in composition. The instant disclosure of these two nucleic acids thus does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from other compounds are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings

sufficient to enable one of skill to isolate and identify the polynucleotides encompassed: there is no guidance in the art as to what the defining characteristics of IFN-L might be. Thus, no identifying characteristics or properties of the instant polynucleotides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of two polynucleotide sequences is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-8, 10, 11, and 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims encompass molecules identified by hybridization. However, hybridization conditions are not defined in the specification: only examples are provided on p. 18.

12. Claims 2-8, 10, 11, and 43-45 are further rejected under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of "an activity of the polypeptide". No such activities are set forth in the specification.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
August 22, 2001

Gary L. Kunz
GARY L. KUNZ
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